K042779

OCT 2 1 2004

510(k) Summary

Radiotherapy Solution Based on CR

Common/Classification Name: Radiotherapy Cassettes for Computed Radiography, 21 CFR 892.1630

Agfa Corporation
10 South Academy Street
Greenville, SC 29602-9048

Contact: Jeffery A. Jedlicka, Prepared: August 9, 2004

A. LEGALLY MARKETED (PREDICATE) DEVICES

The **Radiotherapy Solution Based on CR** is substantially equivalent to the PoRT Cassette (K032654) in regard to its indications for use and cassette characteristics, and to the CR25.0 in regard to the image acquisition and processing characteristics (K041701). The **Radiotherapy Solution Based on CR** should be considered as an accessory to the CR25.0, as was the case for the PoRT Cassette with respect to the PcCR device. K032654 was cleared by FDA as an accessory under regulation 21 CFR 892.1630 (product code IXK), so presumably this is the appropriate regulation and product code for the present product as well.

B. DEVICE DESCRIPTION

The **Radiotherapy Solution Based on CR** allows the application of Portal Imaging in a very wide dose range (1 MU – 400 MU's and higher) by using two different Portal Imaging Cassette types, which are optimised for image quality at their intended dose range. The **Radiotherapy Solution Based on CR** supports both low- and high-dose applications (sometimes called localisation and verification portal imaging).

Not only does the system enable the acquisition of the images under the typical Radiotherapy conditions, the specific requirements for these images are also met which allows their use by the typical "next-in-line" radiotherapy applications. Typical "next-in-line" applications for simulation imaging are, for instance, image comparison and bloc compensator/MLC calculations. For portal imaging, a typical "next-in-line" application is image comparison with a reference image (this can be a simulation image or DRR; comparisons are made between hardcopy prints or on a digital workstation).

C. INTENDED USE

The **Radiotherapy Solution Based on CR** is substantially equivalent to the PoRT Cassette by Orex (K032654) in regard to its indications for use and cassette characteristics, and to the Agfa CR25.0 in regard to the image acquisition and processing characteristics (K041701). The **Radiotherapy Solution Based on CR** should be considered as an accessory to the CR25.0, as was the case for the PoRT Cassette with respect to the PcCR device (K003256). K032654 was cleared by FDA as an accessory under regulation 21 CFR 892.1630 (product code IXK), so presumably this is the appropriate regulation and product code for the present product as well.

D. SUBSTANTIAL EQUIVALENCE SUMMARY

The **Radiotherapy Solution Based on CR** has a similar, but not identical, indications for use statement as the legally marketed predicate devices. However, the differences are minor and do not alter the fact that the devices clearly have the same intended use. The **Radiotherapy Solution Based on CR** has the same technological characteristics as the predicate devices. This premarket notification has described the characteristics of the device in sufficient detail to assure substantial equivalence. Sample clinical images are provided as confirmatory evidence that the device is equivalent to the legally marketed devices.

E. TECHNOLOGICAL CHARACTERISTICS

The technological characteristics are the same in the proposed and legally marketed predicate devices.

F. TESTING

The **Radiotherapy Solution Based on CR** has been tested for proper performance to specifications through various in-house reliability and imaging performance demonstration tests. Clinical performance has been tested in the typical environment of a clinical radiotherapy department, and sample clinical images have been provided in this 510(k).

G. CONCLUSIONS

This 510(k) premarket notification submission has demonstrated Substantial Equivalence as defined and understood in the Federal Food Drug and Cosmetic Act and various guidance documents issued by the Center for Devices and Radiological Health.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 2 1 2004

Agfa Corporation
% Mr. William Sammons
Project Engineer
Underwriters Laboratories, Inc.
12 Laboratory Drive
Research Triangle Park, NC 27709

Re: K042779
Trade/Device Name: Radiotherapy Solution Based on CR25.0
Regulation Number: 21 CFR 892.1630
Regulation Name: Electrostatic x-ray imaging system
Regulatory Class: II
Product Code: 90 IXK
Dated: October 1, 2004
Received: October 6, 2004

Dear Mr. Sammons:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K042779

Device Name: Radiotherapy Solution Based on CR25.0

Indications For Use:

The Radiotherapy Solution Based on CR25.0 is indicated for producing simulation and verification (portal) radiotherapy images to aid in radiation therapy planning and quality control.

Prescription Use X (Part 21 CFR 801 Subpart D)

~~AND~~/OR

Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

David A. Feygin

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K042779